

### **REMARKS**

The Office Action of July 14, 2008 has been carefully reviewed and this paper is Applicants' response thereto. Claims 1-11, 13-21, 23, 28-29, 32, 37-38, and 43-48 are pending. Claims 1-11, 13-21, 23, 28-29, 32, 37-38 and 43-48 stand rejected.

#### **Claim Rejections Under 35 USC §102/§103**

*Claims 1-11, 13-21, 23, 28-29, 32, 37-38 and 43-46 are rejected under 35 USC §102(b) as being anticipated by Fischell, U.S. Patent No. 6,128,538 ("Fischell"), or in the alternative, under 35 USC §103(a) as being unpatentable over Fischell.* Applicants respectfully traverse the rejections.

Independent claim 1 recites the claimed feature of "preventing the therapy device from delivering therapy to the patient for a predetermined quantity of block counts after the therapy device has been activated, wherein the predetermined quantity of block counts is configured to allow the seizure detection algorithm to stabilize." (Emphasis Added). It is respectfully submitted that Fischell does not disclose this claimed feature. In fact, Fischell makes no mention of stabilizing a detection algorithm – indeed the terms stable or stabilize are not found in Fischell. Instead, Fischell merely points out that the detection algorithm may be set so it will not immediately react to a single sensed signal but instead will wait until there are a sufficient number of sensed signals so as to avoid providing a false positive. This falls short of disclosing the recited stabilizing of the detection algorithm. Furthermore, there is nothing in Fischell (or anything else of record) to suggest that the detection algorithm of Fischell requires or would benefit from a stabilizing period. Thus, it is relatively clear that Fischell does not disclose, inherently or otherwise, the above recited feature of claim 1. Therefore, for at least this reason, Fischell does not anticipate independent claim 1 under 35 USC §102(b) and is allowable for at least this reason.

Next, the Office Action goes on to say that in the alternative, it would have been obvious to have the algorithm stabilize as it is allegedly well known to do so and therefore independent claim 1 is unpatentable over Fischell under 35 USC §103(a). Applicants respectfully disagree with the Office Actions assertion.



Applicants respectfully submit that Office Actions statement is conclusory because no support has been provided to show why it would be obvious to include a stabilizing period in the detection algorithm of Fischell. The Office Action merely states on Page 4 “It is obvious/well known to have some time for the algorithm to stabilize such as 2 seconds so the algorithm can correctly detect a seizure.” Furthermore, the Office Action states on Page 8:

Fischell discloses that the detection algorithm contains an event density counter/detector algorithm that determines if there have been enough events in the most recent time period to notify the central processor that a real event has taken place to eliminate the number of false positives by eliminating short uncorrelated bursts (Col. 19, ll. 19-32). By eliminating false positives the system is allowing for the signal to stabilize and thus allowing for the detection to have a stabilized signal, thus effectively stabilizing the detection algorithm.

Applicants respectfully disagree with the Office Action’s assertion that the event density counter/detector algorithm discussed in Fischell enables a seizure detection algorithm to stabilize as claimed in independent claim 1. As stated above, Fischell makes no mention of stabilizing a detection algorithm. In fact, the terms stable or stabilize are not found in Fischell. Instead, Fischell merely points out that the detection algorithm may be set so it will not immediately react to a single sensed signal but instead will wait until there are a sufficient number of sensed signals so as to avoid providing a false positive. This falls short of disclosing the recited stabilizing of the detection algorithm. Applicants respectfully submit that the Office Action has not satisfied the requirement of providing a logical rationale to support the rejection. *KSR Int’l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007) (“To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).”). Importantly, there has been no support provided that shows the detection algorithm of Fischell could be stabilized or that it would benefit from stabilizing. Thus, any suggestion that it would be obvious to include the above recited feature of claim 1 necessarily lacks support. Accordingly, Fischell does not support a *prima facie* case of obviousness with respect to claim 1 and claim 1 is patentably distinct in view of Fischell.

Independent claims 14, 43 and 45 recite features similar to the features discussed above with respect to claim 1 and, therefore, are patentably distinct over Fischell for at least the reasons



that claim 1 is patentably distinct.

Claims 2-11, 13, 15-20, 23, 44 and 46 depend from one of the independent claims 1, 14, 43 and 45 and, therefore, are patentably distinct for at least the reasons that the independent claims 1, 14, 43 and 45 are patentably distinct and for the additional features recited therein.

*Claims 28-29, 32 and 37-38 are rejected under 35 USC §103(a) as being unpatentable over Fischell in further in view of Aimone, U.S. Patent 5,433,737. Applicants respectfully traverse the rejections.*

Independent claims 28, 29, 32, 37, and 38 recite features similar to the features “determining whether the programming information can result in delivery of therapy with a number of stimulations per detection being above a predetermined limit of stimulations per detection” and “preventing the therapy device from being configured according to the programming information if it could result in delivery of a number of stimulations per detection above the predetermined limit of stimulations per detection” as recited in claim 28.

Applicants respectfully submit that the Office Action has not shown where in Fischell these claimed features may be found. In the current Office Action, for the rejections of independent claims 28, 29, 32, 37, and 38, the Office Action merely states on Page 6 “Fischell teaches the claimed invention but not disclose an error handling procedure for parameters based on inputted data.” Therefore, Applicants respectfully submit that if the current rejections of independent claims 28, 29, 32, 37, and 38 are maintained that the Office Action specifically address where these features are found in the cited references. Thus, for at least this reason claims 28, 29, 32, 37 and 38 are patentable over Fischell and Aimone.

In addition, claim 32 further recites the additional features of “calculating parameters that will be used to control a stimulation ON time” and “providing programming information based on the calculated parameters for configuring the therapy device to deliver therapeutic treatment to the body via the therapy delivery element.” The Office Action has failed to provide any support for the suggestion that Fischell or Aimone discloses, teaches, or suggests these features. Indeed, the disclosure in Fischell regarding stimulation is relatively terse – the vast majority of Fischell is directed to signal processing and little is said about stimulation. Applicants have been unable to find any mention of such calculating. Furthermore, as Fischell does not contemplate the idea of “calculating parameters that will be used to control a stimulation ON time,” Fischell



necessarily cannot disclose, teach, or suggest "providing programming information based on the calculated parameters for configuring the therapy device to deliver therapeutic treatment to the body via the therapy delivery element." Moreover, Applicants respectfully submit that Aimone does not make up for the deficiencies in Fischell. The rejection has simply failed to address these features in a sufficient manner and therefore has failed to make a *prima facie* case of obviousness with respect to claim 32 for this additional reason. Accordingly, for at least the above reasons withdrawal of this ground of rejection is respectfully requested.

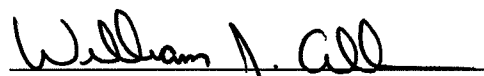
*Claims 47 and 48 are rejected under 35 USC §103(a) as being unpatentable over Fischell in view of Aimone as applied to claim 29, and further in view of Archer, et al., U.S. Patent No. 6,690,974. Applicants respectfully traverse the rejections.*

Claims 47 and 48 ultimately depend from independent claim 29 and are therefore patentably distinct for at least the reasons as independent claim 29 and for additional features recited therein.

All rejections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance. If any matters can be addressed via telephone, the Examiner is invited to contact the undersigned at the number provided below.

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Respectfully submitted,



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